

REMARKS

Claims 1-25 were pending in the present application. By the amendment submitted herewith, claims 1, 18, 20 and 22 are amended to particularly point out and distinctly claim certain embodiments encompassed by the invention. Support for the present amendments may be found in the application as originally filed, for example, in the specification at page 3, lines 4-6; at page 8, lines 27-28; at page 10, lines 8-11; and in the Drawings at Figures 1C, 2C, 3C, 4C, 5C, and 6C; with regard to which it is submitted that disclosure of replacing the test stimulus with a mask, or blocking the user's line of vision to the test stimulus with a mask, are readily understood to constitute masking the entire test stimulus. Accordingly, no new matter is introduced by way of the present amendment.

REJECTIONS UNDER 35 U.S.C. §103

A. The PTO rejects claims 1, 2, 4-6, 9, 10, 12-16, 18, 22, 24, and 25 under 35 U.S.C. §103 for alleged non-obviousness over Polat et al. (U.S. Patent No. 6,876,758) in view of Hongo *et al.* (U.S. Patent No. 5,345,944). The Examiner asserts that Polat et al. teach a test of visual perception, but concedes that Polat et al. fail to disclose such features of the present claims as masking a stimulus, repeating the stimulus for a range of durations, presenting a focal point to the user before presenting the stimulus, calculating both an error rate for each stimulus and an error rate curve for the user, uniform time intervals between repetitive exposures, and a mask comprising at least one filled circle. The Examiner asserts, however, that Hongo et al. remedy these deficiencies of Polat et al., citing in particular Hongo et al. at column 2, lines 5-18 and 24-28; column 3, lines 36-48; column 6, lines 19-26; and Figures 7, 8, and 11. The Examiner further asserts that it would have been obvious to modify the method of Polat et al. according to the disclosure in Hongo et al. since doing so would provide a means of controlling exposure of the stimulus to the user, in order to obtain an accurate response time measurement.

Applicants respectfully traverse these grounds for rejection. The instant embodiments are directed in pertinent part to a method of assessing cognitive impairment of a user, comprising the steps of (a) presenting a visual test stimulus, (b) masking the test stimulus by placing a mask over or in place of (*i.e.*, replacing) the entire visual test stimulus, (c)

measuring a response, (d) repeating steps (a)-(c) to develop a user profile, and (e) comparing the user profile to a reference profile, as recited.

It is submitted that a person having ordinary skill in the art would not, at the time of filing the instant application, have had any reasonable expectation of successfully combining the teachings of Polat et al. and Hongo et al., to arrive at the present subject matter. For reasons given herein, the disclosures of Polat and Hongo are insufficient to render the presently encompassed subject matter obvious to the skilled person with the requisite reasonable expectation of success, *inter alia*, where the prior art failed to contemplate completely masking a visual stimulus in a manner that blocks visual processing of the visual stimulus by a user. The disclosure of Polat et al. merely relates to a system for improving a user's visual perception that is deployed for use over a communications network. The disclosure of Hongo et al. relates to a system and apparatus for the medical diagnosis of diseases related to brain function (e.g., Alzheimer's Disease) that involves measuring the user's eye (and preferably head) movement over an image. By monitoring eye (and head) movement, the apparatus of Hongo et al. calculates a "line of sight", which is in turn used to determine a point of fixation, *i.e.*, a point where the subject is focusing his or her vision. The PTO fails, however, to show that the combination of Polat and Hongo would suggest every feature of the present claims to the skilled person.

According to Hongo et al., an image is presented to the subject with a task for diagnosis. The image includes a pattern containing features which are identified by the subject during completion of the task. For example, the image may include a pattern containing circles, triangles and squares, and the task is to count the number of circles in the image. The apparatus of Hongo then generates a mask for masking a portion of the task image displayed at the fixation point, as is determined according to the calculated line of sight (Hongo, column 6 lines 3-16). The mask is then removed after a prescribed time period, T_r , and presentation of the complete original image is resumed (col 6 lines 20-27), without the mask. The apparatus continues to calculate the line of sight as the subject counts the number of circles (to complete the task) together with a fixation time distribution, locus of the line of sight and eye movement velocity

distribution. These measures are used to determine the possibility and degree of advance of dementia.

Although Hongo et al. thus disclose means for presenting a visual test stimulus, Hongo et al. fail to disclose or suggest, *inter alia*, masking the entire visual test stimulus, for example by replacing the test stimulus or placing a mask over it, as is recited in step (b) of claims 1, 18, 20 and 22 in the instant application. Hongo et al. merely disclose masking a portion of the test stimulus, which portion is specifically selected by the apparatus to be in the line of sight (*i.e.*, at the point of fixation) of the subject. The mask in Hongo et al does not obstruct the subject's view of the remainder of the visual test stimulus, thus permitting the apparatus to ascertain, in the subject, the fixation time distribution and eye movement velocity distribution even as the subject completes the task (counting the number of circles in the test stimulus).

It is therefore submitted that Hongo et al., alone or in combination with Polat et al., necessarily fail in any way to contemplate the presently recited step of masking a test stimulus by replacing a visual test stimulus or placing a mask over the entire visual test stimulus, because according to Hongo an unmasked portion of the stimulus must remain visible in order that the subject may perform the task. Hongo et al. thus teach away from "masking" according to the instant application, in which masking "occurs by replacing [the test stimulus] with a mask" or "by blocking the user's line of vision to the test stimulus using a mask." (specification, page 3, lines 4-6).

In other words, Hongo et al merely disclose a mask that occludes only a portion of the presented ("task") image. This partial occlusion can be readily distinguished from the masking step in the instant embodiments, according to which the masking step involves replacing the entire visual test stimulus with a mask, or blocking the user's vision of the entire test stimulus using a mask (*e.g.*, specification, page 3, lines 4-6). The masks illustrated in the drawings of the present application exemplify embodiments of the invention, and unlike anything contemplated by Hongo whether taken alone or in combination with Polat, each mask of the present application completely obstructs a user's sight of the entire visual test stimulus (see Figures 1C, 2C, 3C, 4C, 5C and 6C). In addition, the contrary, partial mask of Hongo et al. differs further from the masks of the present application in that the mask of Hongo is temporary

and varies in type, size and duration (Hongo et al., column 6, line 34-36), and is presented multiple times for a particular task image at varying locations which are dictated according to the line of sight of the user's eye, as calculated by the apparatus (Hongo et al., column 2, line 24-27). If anything, Hongo et al. thus teach away from the presently claimed subject matter, because in order to practice the method of Hongo the test subject continues to view the unmasked portion of the visual stimulus, while in the instant methods the visual stimulus is entirely occluded by the mask, thereby halting visual stimulation.

The differences between the mask of the instant invention and the mask in Hongo et al. can be better understood by reference to the purpose of the mask in the respective systems. The function of the mask image in Hongo et al. is to trigger a rapid movement of the eyes (a saccade) to another location on the task image (column 6, line 48-57), in order to give an indication as to the existence and degree of dementia. In contrast, the function of the mask in the instant embodiments is to prevent any further visual processing of the test stimulus or any part of it, by masking the *entire* stimulus. The PTO alleges that, per the teachings of Hongo et al., the use of a mask would provide a means of controlling the exposure of stimulus to the user in order to obtain an accurate measure of a response time. In traversal the applicants respectfully submit that this is not the case, where according to Hongo the fact that only partial masking of the stimulus takes place means that the subject in Hongo is persistently exposed to the stimulus. By way of contrast, according to the instant embodiments, the mask *per se* has no influence over the subject's response time, but instead merely aids in terminating the user's mental processing of the test stimulus.

The asserted mask in Hongo et al. is therefore different in both type and function from the mask used in the step of masking according to the instant claims. According to the present methods, the mask occludes (*i.e.*, is placed over) the entire test stimulus or replaces the entire test stimulus. Given the differences between the mask (and its function) as disclosed in Hongo et al and the mask (and its function) as recited in the step of masking in the instant claims, it is submitted that Hongo et al fail to remedy the deficiencies in Polat et al, and that the masking step as recited in the instant embodiments would not have been obvious to one of ordinary skill in the art at the time the presently claimed invention was made.

Furthermore with respect to the rejections of claims 2, 9 and 22, and as also noted above, applicants submit that in the method of Hongo et al., all or at least part of a test stimulus (task image) *remains visible* while it is the *mask* that is repeatedly presented at various locations that are dependent on the eye movement of the user. By way of contrast, in the practice of the instant embodiments it is the *visual test stimulus* that, by virtue of being completely masked during the recited step of masking, is repeatedly presented for a range of predetermined durations (claims 2, 22), which in certain embodiments are separated by a uniform time interval (claim 9). In view of these recited features, it cannot be said that Hongo et al teach or suggest the subject matter of the instant claims.

Applicants therefore submit that the PTO has not established a *prima facie* case of obviousness. (See *In re Mayne*, 104 F.3d 1339, 1341-43 (Fed. Cir. 1997), PTO has the burden of showing a *prima facie* case of obviousness). The PTO must show that all of the claimed elements were known in the prior art, that a person skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and that the combination would have yielded nothing more than predictable results to such a skilled person. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385. Additionally, the PTO must show that the person skilled in the art would have had a reasonable expectation of success in arriving at the claimed subject matter. M.P.E.P. § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986)).

In the instant case, including for reasons given above and previously made of record, it is submitted that the PTO fails to provide evidence or reasoning as to why the skilled person would reasonably have expected *successfully* to combine the recited elements. *Inter alia*, the presently recited step of masking relates to unpredicted advantages that derive from complete occlusion or replacement of the visual test stimulus and that were nowhere suggested in the prior art. For these and other reasons discussed herein, it is therefore submitted that the presently claimed subject matter is patentably nonobvious. Favorable reconsideration of the instant claims and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

B. The PTO rejects claims 3, 19, 21 and 23 for alleged non-obviousness over Polat et al. and Hongo et al. as above, in view of Shekels (U.S. Patent No. 2,564,794). The Examiner concedes that Polat et al. and Hongo et al. fail to disclose presenting a focal point stimulus to the user before presenting the visual test to the user, but asserts that Shekels discloses such presentation. The Examiner further asserts that it would have been obvious to modify the combination of Polat et al. and Hongo et al. to provide the focal point stimulus, as per the teachings of Shekels, alleging that it is well known in the art to provide a focal point stimulus when performing eye testing.

Applicants traverse these grounds for rejection. Shekels fails to remedy the deficiencies of Polat and Hongo, which are discussed above, such that even the combination of Polat, Hongo and Shekels fails to suggest the subject matter of the instant claims. Shekels merely discloses the use of a target employed as a focal point for the eye, being of contrasting color to the remainder of the diffusion plate, or a mirror. However, the target in Shekels is not presented to the user before the presentation of a test stimulus according to the instant claims. Rather, the Shekels target is part of the testing apparatus and is itself the focal point of the visual test (column 4, lines 14-20).

Notwithstanding this distinction, the applicants respectfully submit that claims 3, 19, 21 and 23 are patentable by reason of their dependency on patentable base claims. In this regard, and for reasons given above, Shekels fails to cure the deficiencies of Polat and Hongo with respect to a method of assessing cognitive impairment of a user that comprises, in pertinent part, presenting a focal point stimulus to the user, then presenting a visual test stimulus for a pre-determined exposure duration, and masking the test stimulus by placing a mask over or in place of the entire visual test stimulus. The PTO thus fails to establish a case of *prima facie* obviousness where no evidence or reasoning has been presented as to why a person skilled in the art would, at the time of filing, have combined the elements as presently claimed by known methods, with no change in their respective functions, and in a manner whereby the combination would have yielded nothing more than predictable results to such a skilled person. “A patent composed of several elements is not proved obvious merely by demonstrating that each element

was, independently, known in the prior art.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 127 S.Ct. 1727, 82 USPQ2d 1385, 1395 (2007), No. 04-1350 4, 14, (U.S. April 30, 2007).

Reconsideration and withdrawal of the rejections are therefore respectfully requested.

C. The PTO rejects claims 7, 8, and 11 for alleged obviousness over Polat et al. and Hongo et al. as above, in further view of Rootzen et al. (U.S. Patent No. 5,381,195). The Examiner concedes that Polat et al. and Hongo et al. fail to disclose calculating a mean response time and a stimulus exposure time of between 10ms and 300ms, but asserts that Rootzen et al. teach both of these features. The Examiner alleges that it would have been obvious to modify the combination of Polat et al. and Hongo et al. with the teachings of Rootzen et al. to provide a means for accurately determining the attention of the user, thereby determining user impairment.

The rejection is traversed. Rootzen et al. fail to remedy the deficiencies of Polat and Hongo, which are discussed above, such that even the combination of Polat, Hongo and Rootzen et al. fails to suggest the subject matter of the instant claims. Briefly, Rootzen et al. fail to cure the deficiencies of Polat and Hongo with respect to a method of assessing cognitive impairment of a user that comprises, in pertinent part, developing a user profile by repeatedly (a) presenting a visual test stimulus for a pre-determined exposure duration, and (b) masking the test stimulus by placing a mask over or in place of the entire visual test stimulus, and further calculating a mean response time for each pre-determined test stimulus exposure duration.

Without acquiescing to the rejection of claims 7, 8 and 11, applicants also refer the Examiner to the rebuttal arguments previously made of record in applicants’ submission of May 5, 2008, in which many differences between the instant subject matter and the Rootzen et al disclosure were pointed out. It is submitted that the PTO has not responded specifically to these rebuttal arguments as previously put forth.

For the PTO’s benefit, it is again noted that the disclosure of Rootzen et al concerns a method for determining a response time window for each participant, based on the participant’s own data or on estimates from a population mean (column 6 lines 21-41), where the response time window specifies upper (RT_{max}) and lower (RT_{min}) limits of the time in which a

participant is expected to make a legitimate judgment as to whether or not a visual stimulus was seen. The initial response time window for a participant is adjusted over the course of the test according to the pattern of false positive responses (*i.e.*, errors of detection). The critical performance measure according to Rootzen et al. is the final response time window which is represented by two individual response times, the upper limit of the response time window (RT_{\max}) and the lower limit of the response time window (RT_{\min}).

By contrast, according to the subject matter of the instant claims, the relevant response time data are the participant's actual response times in reaction to each test stimulus presented at each of the predetermined test stimulus exposure durations. The response time performance measures of significance to the instant embodiments (*e.g.*, claims 7 and 8) are the means of the response times to the test stimuli presented at each of the predetermined test stimulus exposure durations. The mean response time at each test stimulus exposure is then used to plot a curve that charts the mean response time relative to the pre-determined test stimulus exposure durations (*e.g.*, claim 8); this curve provides the "user profile", *i.e.*, the participant's performance profile. This user profile, as expressly recited in the instant claims and representing a participant's performance profile as just described, is neither taught nor in any way suggested by Rootzen et al. The PTO further fails to provide evidence or reasoning as to how the prior art suggests this subject matter of the present claims.

In any event and notwithstanding the above, applicants respectfully submit that claims 7, 8 and 11 are patentable by reason of their dependency from patentable independent claim 1. Reconsideration and withdrawal of the rejection are therefore requested.

D. The PTO rejects claim 17 for alleged obviousness over Polat et al. and Hongo et al. as above, in view of Bachman et al. (U.S. Patent No. 4,241,942). The Examiner asserts that it would have been obvious to modify the combination of Polat et al. and Hongo et al. to include a mask having a plurality of lines, as allegedly disclosed in Bachman, alleging further that it is well known in the art to utilize various types of masks during a visual test.

Applicants respectfully traverse these grounds for rejection. Bachman fails to remedy the deficiencies of Polat and Hongo, which are discussed above, such that even the

combination of Polat, Hongo and Bachman fails to suggest the subject matter of the instant claims. Briefly, Bachman fails to cure the deficiencies of Polat and Hongo with respect to a method of assessing cognitive impairment of a user that comprises, in pertinent part, developing a user profile by repeatedly (a) presenting a visual test stimulus for a pre-determined exposure duration, and (b) masking the test stimulus by placing a mask over or in place of the entire visual test stimulus, wherein the mask comprises an image having a plurality of curved lines.

The PTO misapplies Bachman and clearly errs in asserting that the mask of Bachman “is utilized to prevent a user from seeing the underlying material, in the same way the current invention’s mask prevents the user from seeing the underlying visual stimulus.” (Action, page 5, emphasis added). It is respectfully submitted that the mask of Bachman certainly does not work “in the same way” as the mask recited in the instant claim. On this point, applicants note that “[a]ll words in a claim must be considered in judging the patentability of the claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). See M.P.E.P. §2143.03. As such, when taken as a whole the subject matter of the instant claims is readily distinguishable over Bachman.

The Examiner is again requested to reconsider applicants’ submission of May 5, 2008, in which the shortcomings of Bachman are discussed at length. Applicants are puzzled by the PTO’s silence with regard to applicants’ arguments of record distinguishing Bachman. Clarification is requested.

Briefly, it is submitted that the skilled person would not consider it possible to employ a masking material as described by Bachman in any embodiment of the present invention, where Bachman clearly teaches away from step (d) of the instant claim (repeating the steps of presenting and masking). Specifically, once the mask of Bachman is removed a first time, it is destroyed (Bachman, column 2, lines 57-60), thereby obviating the possibility of performing the recited step of “repeating” (step (d)), which refers to repeating the step of “masking” (step (b)) according to the presently claimed subject matter. Therefore, and contrary to the assertion made by the PTO, when all the words of the instant claim are considered, as is required under *In re Wilson*, it is clear that the mask of Bachman cannot be used “in the same way” as the mask according to the present embodiment.

For reasons also previously made of record, it is noted that the field of invention in Bachman is in the area of lotteries, games and contests, and that Bachman, whether taken alone or in any combination with one or more of Polat and Hongo, does not disclose or even remotely suggest any applications of the subject matter disclosed therein to the field of cognitive testing or assessment. Applicants respectfully submit that the field of invention in Bachman is so distinct from the instant invention that a person skilled in the art of assessing cognitive impairment would not identify the Bachman citation as being of relevance. Notwithstanding the lack of relevance in the art, the Bachman citation does not render the invention obvious for other reasons as made of record and discussed herein.

The Examiner asserts that even though the “mask” disclosed in Bachman is not utilized during a visual or cognitive test, the mask in Bachman is used to prevent a user from seeing the underlying material, in the same way as the mask according to applicants’ invention prevents the user from seeing the underlying visual stimulus.

Applicants respectively traverse this assertion and submit that it is beside the point and has no relevance to the instant claim. In Bachman, a patterned layer is interposed between the card stock and the indicia, or between the indicia and elastomeric mask, or both between the card stock and the indicia and between the indicia and the elastomeric mask. The objective of the patterned layer disclosed by Bachman is to prevent recognition of the indicia, *e.g.*, when using a photocopier, by rendering light rays which may be transmitted from the indicia to the paper of the photocopy process indistinguishable from the light rays transmitted from the patterned layer to the paper, so that *prior to removal* of the patterned mask layer, the image which appears on the paper of the photocopy process does not disclose the hidden indicia (Bachman, column 2, lines 17-27).

The patterned layer of Bachman is, however, “invisible to visual examination” even while effectively concealing the underlying visual indicia (see column 5, lines 43-46). In addition to recognizing that the patterned layer of Bachman is incapable, for reasons discussed above, of being used for *repeated* steps of presenting, masking and measuring according to the instant claims, applicants submit that the skilled person would also recognize that the function of the patterned layer according to Bachman is quite different from that of a mask according to the

present subject matter. The patterned layer of Bachman is “invisible to visual examination”, and can be removed by the user in order to view the underlying visual indicia *for any desired time period*. By contrast, in the presently claimed subject matter a user views the test stimulus only for a pre-determined test stimulus exposure duration that is followed by masking, measuring and repeating steps. Contrary to the assertion found in the Action, the function of the patterned layer of Bachman is clearly different from the function of the mask in the present embodiments, which is expressly to be placed over or in place of the visual test stimulus to preclude visibility to the user of the test stimulus, and which may comprise a useful image (*e.g.*, specification at page 4, line 31 through page 5, line 2). Bachman, whether taken alone or in combination with Polat and Hongo, thus fails to disclose or in any way contemplate each recited feature of the present claim.

In view of the foregoing, it is submitted that Bachman is not relevant prior art and that in any event, the disclosure of Bachman teaches away from the present invention such that the prior art fails to render the presently claimed subject matter obvious. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103 are therefore respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to telephone the applicants' undersigned representative should there remain any unresolved issue concerning this application.

Respectfully submitted,

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